MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Individual Safety Report

3141499-0-00-01

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981007-107013856

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
UNKNOWN In confidence	39 Year(s)	[X] female [ ] male	____ lbs or UNK ____ kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [X] death ??/??/?? (mo/day/yr)
- [ ] life-threatening
- [ ] hospitalization - initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of event: UNK (mo/day/yr)

4. Date of this report: 10/12/98 (mo/day/yr)

5. Describe event or problem

Report published in American Journal of Emergency Medicine 16(5), 1997 Annual Report of Poison Control Centers TESS: pp.443-497 (case 216) of a 39 year old, female, who ingested acetaminophen and acetaminophen with codeine chronically for two months for headache (dose unknown). Her other medications included aspirin, ampicillin, theophylline, lovastatin and carisoprodol. She presented to the emergency department with evidence of dehydration and an upper gastrointestinal bleed. She was admitted to the intensive care unit. Initial laboratory values: acetaminophen -51 ug/mL; salicylate -2.5 mg/dL; INR >10, creatinine- 2.4 mg/dL and AST 144U/1L. Twenty hours after admission acetaminophen level was 24ug/mL. N-acetylcysteine was started and repeat laboratory values included: AST 6,800 U/L and ALT 6,700 U/L. The next day she developed respiratory distress, requiring intubation, received vasopressors and glucose supplements and had increasing PT with bleeding at several sites. She died on the fourth day of admission. Chronicity was chronic. Additional information has been requested.

6. Relevant tests/laboratory data, including dates

Initial laboratory values: acetaminophen -51 ug/mL; salicylate -2.5 mg/dL; INR >10, creatinine- 2.4 mg/dL and AST 144U/1L. Twenty hours after admission acetaminophen level was 24ug/mL. Repeat laboratory values: AST 6,800 U/L and ALT 6,700 U/L.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Taking acetaminophen and acetaminophen with codeine chronically for 2 months for headaches.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL WITH CODEINE TABLETS (ACETAMINOPHEN & CODEINE)

#2

2. Dose, frequency & route used

#1 Unknown., Unknown, ORAL

#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))

#1 Unknown

#2

4. Diagnosis for use (indication)

#1 headache

#2

5. Event abated after use stopped or dose reduced

#1 [ ] yes [ ] no [X] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)

#1 UNK

#2

7. Exp. date (if known)

#1 UNK

#2

8. Event reappeared after reintroduction

#1 [ ] yes [ ] no [X] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

9. NDC # - for product problems only (if known)

NA

10. Concomitant medical products and therapy dates (exclude treatment of event)

1) ACETAMINOPHEN	Unknown
2) ASPIRIN	Unknown
3) AMPICILLIN	Unknown
4) THEOPHYLLINE	Unknown
5) LOVASTATIN	Unknown
6) CARISPRODOL	Unknown

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)

R. W. JOHNSON PHARM. RESEARCH INSTITUTE
DIV. OF ORTHO PHARMACEUTICAL CORPORATION
ROUTE 202, P.O. BOX 300
RARITAN NJ 08869-0602

(Informing unit)

2. Phone number: (908) 704-4600

3. Report source (check all that apply)

- [ ] foreign
- [ ] study
- [X] literature
- [ ] consumer
- [X] health professional
- [ ] user-facility
- [ ] company representative
- [ ] distributor
- [ ] other:

4. Date received by manufacturer (mo/day/yr): 08/28/98

5. (A) NDA # 85-055
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)

- [ ] 5-day
- [X] 15-day
- [ ] 10-day
- [ ] periodic
- [X] Initial
- [ ] follow-up # ____

8. Adverse event term(s)

1) DEHYDRATION
2) GI HAEMORRHAGE
3) DYSPNOEA
4) THERAPEUTIC RESPONSE INCREASED

9. Mfr. report number

981007-107013856

E. Initial reporter

1. Name, address & phone #

TOBY L. LITOVITZ, M.D.
AMERICAN ASSOC OF POISON CONTROL CENTERS
3201 NEW MEXICO AVENUE, SUITE 310
WASHINGTON DC 20016
Phone # :202-362-3867

OCT 15

2. Health professional? [X] yes [ ] no

3. Occupation: Physician

4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk

Form 3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

Individual Safety Report
3141499-0-00-02

Continuation Sheet for FDA-3500A Form

Mfr. report # : 981007-107013856

Source of report (Literature)

Title	: 1997 ANNUAL REPORT OF THE AMERICAN ASSOCIATION OF POISON CONTROL CENTERS TOXIC EXPOSURE SURVEILLANCE SYSTEM
Author	: TOBY L. LITOVITZ, ET AL
Year	: 1998
Edition	: 16(15)
Journal Title	: AMERICAN JOURNAL OF EMERGENCY MEDICINE
Page No.	: 443 To 497

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